

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MAR 14 1997

Mr. Edward W. Raleigh
DuPont Agricultural Products
Experimental Station
P.O. Box 80402
Wilmington, Delaware 18880-0402

Dear Mr. Raleigh:

This letter is in regard to your genetically modified soybean lines, about which you initiated consultation with the agency on January 24, 1995. These new soybean varieties have been modified to produce increased levels of oleic acid in the seed oil by sense suppression of the gene GmFad2-1 which encodes a δ -12 desaturase enzyme.

As part of bringing your consultation with FDA regarding this product to closure, you submitted a summary of your safety and nutritional assessment of the new soybean varieties on August 28, 1996. On December 5, 1996, you discussed the data and information that support your submission with FDA and proposed a new common or usual name for the oil from the new varieties (High Oleic Soybean Oil). These communications were intended by DuPont to inform FDA of the steps taken to ensure that this product complies with those legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment you have conducted it is our understanding that you have concluded that the new soybean varieties are not materially altered in any respect relevant to food or animal feed safety from soybean varieties currently on the market and that these lines do not raise issues that would require premarket review or approval by FDA. Based on the compositional differences of the oil and its intended use, it is also our understanding that you have concluded that the common or usual name High Oleic Soybean Oil is appropriate to distinguish oil from the new soybean varieties from traditional soybean oil. All materials relevant to this consultation have been placed in a file that has been designated BNF0039 and that will be maintained in the Office of Premarket Approval.

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Based on the information you have presented to FDA, we have no additional questions concerning soybean lines, G94-1, G94-19, and G168, at this time. However, as you are aware, it is DuPont's continued responsibility to ensure that foods the firm markets are safe, wholesome, and in compliance with all applicable legal and regulatory requirements.

Sincerely yours,

/s/

Alan M. Rulis, Ph.D.
Director
Office of Premarket Approval
Center for Food Safety
and Applied Nutrition

cc:HFS-13, HFS-200, HFS-205, HFS-206, HFS-226, HFS-246, HFS-247, HFV-200,
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